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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,537	02/18/2004	Peter Colin Weston Burt	PB60086US2	2234

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,537	BURT ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☒ Claim(s) *1-3 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending.

Specification

Claims 1-3 and 14 are objected to because of the following informalities: a space should be inserted between numerical values and their respective units of measurements (e.g. claim 1, line 4, "1.00mm" should read "1.00 mm"). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al. (WO 96/32150; IDS).

Applicant Claims

Applicant recites (a) a canister for a metered dose inhaler (MDI) have part or all of its internal surfaces coated with one or more fluorocarbon polymers, optionally in combination with one or more non-fluorocarbon polymers, said canister having a wall thickness in the range of 0.55 mm to 1.00 mm; (b) a MDI comprising (1) said canister containing a formulation comprising (i) fluticasone propionate or albuterol sulfate, (ii) hydrofluorocarbon propellant, (iii) or fluticasone propionate in combination with salmeterol xinafoate, (2) metering valve, (3) channeling device, and (4) a crimped cap; and (c) a method of administering an active ingredient to a patient comprising provided the MDI of claim 6 and activating the MDI to deliver an effective amount of at least one active ingredient to a patient.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Ashurst discloses a **MDI having part or all of its internal surfaces coated with one or more fluorocarbon polymers, optionally in combination with one or more non-fluorocarbon polymers**, for **dispensing (i.e. administering) an inhalation drug formulation comprising (a) salmeterol or a physiologically acceptable salt thereof,**

(b) fluorocarbon propellant, and (c) optionally in combination with one or more pharmacologically active agents or one or more excipients (abstract). Ashurst defines MDI as meaning a unit comprising a **can (i.e. canister)**, a **crimped cap covering the mouth of the can**, and a **drug-metering valve** situated in the cap, whereas the term "MDI system" is defined as a MDI also including a **channeling device** (pg. 2, lines 24-26). Preferred formulations contained within in Ashurst's MDI comprise (a) **salmeterol xinafoate and fluticasone propionate or albuterol (or a physiologically acceptable salt thereof)** optionally in combination with another active and (b) a fluorinated propellant, preferably **1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, or mixtures thereof** (pg. 5, lines 13-14 and pg. 6, lines 1-12).

Ashurst teaches that advantageously strengthened aluminum or aluminum alloy MDI cans may be employed, because strengthened cans have a reduced tendency to malform under high temperatures. Strengthened cans include MDI cans having sidewalls and a base of increased thickness and MDI cans comprising a substantially ellipsoidal base (pg. 6, lines 18-20 and 22-25).

Ashurst teaches the fluorinated polymers for use in his invention include polymers made from the following monomers: **tetrafluorethylene (PTFE), fluorinated ethylene propylene (FEP), perfluoroalkoxyalkane (PFA), ethylene tetrafluoroethyylene (ETFE), wherein PTFE, PFA, and FEP are preferred**. Suitable non-fluorinated polymers for use in combination with the fluorinated polymers described above include polyethersulfones, polyphenylene sulfides, polyimides, and polyamides, etc. Preferred fluoropolymer/non-fluoropolymer blends include PTFE/FEP/polyamideimide, PTFE/polyethersulfone, and FEP-benzoguanamine (pg. 7,

lines 4-17). The use of Ashurst's MDIs and MDI systems in the treatment of respiratory disorders (e.g. asthma) is also taught (pg. 10, lines 17-18 and claim 22). Examples 1-64 exemplify the Ashurst's MDIs and the formulations contained therein. Applicant's attention is pointed to Examples 2, 6, 11, 16, 21, etc. wherein standard **0.46 mm thick** aluminum sheet is used to make coated MDI cans. It is understood that wherever Ashurst refers to a standard 12.5 mL MDI cans that said cans have a wall thickness of 0.46 mm.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Ashurst does not anticipate the claims of the instant application, because a wall thickness of between 0.55 mm and 1.00 mm is not taught.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the teachings of Ashurst and use cans having increased wall thicknesses for incorporation into MDIs and MDI systems, because Ashurst teaches that strengthened cans have a reduced tendency to malform under high temperatures. The term "strengthened cans" includes MDI cans having sidewalls and a base of increased thickness. Therefore, the desirability of using canisters coated with fluoropolymers in MDIs and/or MDI systems, wherein said canisters (i.e. cans) have an increased wall thickness would have been apparent to a skilled artisan at the time. The physical characteristics (e.g. size, shape, thickness, etc.) of canisters for use in MDIs are clearly

result specific parameters that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal physical characteristics (e.g. size, shape, thickness, etc.) of a MDI can needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of canister wall thickness would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following rejections are made on the understanding that Glaxo Wellcome, Inc. and SmithKline Beecham Corporation have merged into GlaxoSmithKline, and thus the U.S. Patents below are now commonly owned.

Claims 1-22 (all claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 8-22 of U.S. Patent No. 6,524,555 (USPN '555); over claims 1, 6-52, and 55-65 of U.S. Patent No. 6,131,566 (USPN '566); over claims 1 and 5-30 of U.S. Patent No. 6,143,277 (USPN '277); and over claims 1, 6-16, 20-51, and 55-65 of U.S. Patent No. 6,253,762 (USPN '762). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and thus mutually obvious. The cited claims of USPN '555 and the instant application recite a metered dose inhaler comprising a can wherein part or all of its surface is coated with a polymer composition, said can (i.e. canister) contains a formulation comprising (1) salmeterol xinafoate and/or fluticasone propionate and (2) a fluorocarbon propellant. The polymers recited as coating the canister surfaces include fluorinated polymers (e.g. PTFE), non-fluorinated polymers (e.g. polysulfone), or mixtures thereof. One difference between USPN '555 and the instant application is that USPN '555 does not recite a canister or MDI comprising said MDI having a wall thickness in the range of 0.55 mm and 1.00 mm. It is noted that standard wall thickness of canisters incorporated within the MDIs taught by USPN '555 is 0.46 mm, such as in USPN '555 Examples 2, 6, 11, and 16. It would have been apparent to a skilled artisan that MDI canisters having increased thickness would be more resistant to malformation upon heating. A person of ordinary skill would have been motivated to optimize canister wall thickness to obtain MDIs and canisters having a reduced tendency to malform upon heating. Regarding, the recitation of albuterol sulfate in claim 16 of the instant application, it is noted that the use of a different bronchodilating beta-agonist (albuterol in lieu of salmeterol) would have been

an obvious modification, because a skilled artisan would have had a reasonable expectation of success upon substitution. Furthermore, it is noted that USPN '555 teaches in column 4, lines 19-20 that formulations comprising albuterol or pharmaceutically accepted salts thereof are preferable. Similar reasoning as set forth here is used to reject the claims of the instant application over the other U.S. patents cited above.

The Examiner has noted that the U.S. Patents listed below claim substantially similar subject matter as the instant application and USPN '555. It is incumbent upon the Applicant to review the following patents and file a terminal disclaimer to overcome obviousness-type double patenting when appropriate: USPN 6,511,653; USPN 6,532,955; and USPN 6,546,928.

Conclusion

Claims 1-3 and 14 are objected. Claims 1-22 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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